PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

THE BOARD OF APPEALS AND INTERFERENCES

Appellants	:	Lindsay S. Machan et al.
Application No.	:	09/476,490
Filed	:	December 30, 1999
For	:	STENT GRAFTS WITH BIOACTIVE COATINGS

Examiner	:	Melanie Ruano Tyson
Art Unit	:	3773
Docket No.	:	110129.411
Date	:	October 28, 2008

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' BRIEF

Commissioner:

This brief is in furtherance of the Notice of Appeal, filed in this case on March 5, 2008. The fees required under Section 41.20(b)(2), and any required request for extension of time for filing this brief and fees therefor, are dealt with in the accompanying papers.

I. REAL PARTY IN INTEREST

The real parties in interest in the above-identified application are Angiotech International AG, which is a subsidiary of Angiotech Pharmaceuticals, Inc., and the University of British Columbia, both of which are the assignees of record.

II. RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' legal representative, and the real party in interest are unaware of any appeal or interference which may be related to, directly affect, be directly affected by, or have a bearing on the Board's decision in the present appeal.

III. STATUS OF CLAIMS

There are 56 claims in total in the present application.

Claims 1, 2, 5-10 and 16-56 are canceled. Claims 3, 4 and 11-15 are rejected and subject to this appeal. Appellants request that these claims be considered as a group that stand or fall together.

IV. STATUS OF AMENDMENTS

All amendments have been entered. A Final Office Action was mailed September 5, 2007. In response to this Final Office Action, a Notice of Appeal was filed on March 5, 2008. No amendments have been filed in response to the Final Office Action mailed September 5, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Stent grafts are devices that have been developed not only to hold open anatomical passageways, but also to bridge a diseased portion of such a passageway by forming a non-leaking conduit to transport fluid from one healthy portion of a passageway to another, thus bypassing the diseased portion interposed between the two healthy portions. In particular, for example, a stent graft is commonly used to bypass an aneurysm of the wall of an artery, for example, an abdominal aortic aneurysm, thus maintaining blood flow from a non-diseased portion of artery of acceptable caliber located above the aneurysm to a non-diseased portion of artery of acceptable caliber located below the aneurysm.

Effective use of a stent graft as an alternative passageway to bypass, for example, a diseased portion of a blood vessel, requires a complete and long-lasting seal between the outer surface of the stent graft and the healthy portions of the vessel wall. Such a seal provides long term prevention of perigraft leakage of blood into the space between the stent graft and the diseased portion of the vessel. Effective use of a stent graft further requires that the position of the stent graft within the blood vessel be maintained and that it not be allowed to migrate distally within the blood vessel.

Claims 3, 4, 11, 12, 13, 14 and 15 are pending in the subject application. Claim 3 is the only independent claim. Claims 4 and 11-15 depend either directly or indirectly from independent claim 3.

Independent claim 3 of the subject application is directed to a stent graft comprising an endoluminal stent, a graft, and a vessel wall irritant, such that, when the stent graft is implanted into a blood vessel, the stent graft induces or accelerates an *in vivo* fibrotic reaction in a tissue in the vicinity of the stent graft. Accordingly, a stent graft of claim 3 (and the dependent claims 4 and 11-15) can have no fewer than three elements: (1) an endoluminal stent; (2) a graft: and (3) a vessel wall irritant. The subject application discloses, for example at page 3, lines 26-28, a stent graft that induces adhesion or fibrosis in a blood vessel wall, thus increasing or accelerating adherence of the stent graft to the blood vessel wall. The subject application further discloses, for example at page 4, lines 11-13, a stent graft comprising an endoluminal

stent and a graft, wherein the stent graft induces or accelerates an *in vivo* fibrotic reaction, thereby causing the stent graft to adhere to the blood vessel wall. Yet further, the subject application discloses a stent graft comprising an agent that induces *in vivo* adhesion of the stent graft to blood vessel walls, wherein the adhesion is induced by an increase or acceleration of a reaction between the stent graft and the blood vessel wall, such that the stent graft is fixed within the vessel.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection to be reviewed on appeal are whether claims 3 and 12-15 are anticipated by U.S. Patent No. 6,379,379 (referred to herein as "the '379 Patent") under 35 U.S.C. § 102(e) and whether claims 4 and 11 are unpatentable over the '379 Patent under 35 U.S.C. § 103(a).

VII. ARGUMENT

Rejection under 35 U.S.C. § 102(e)

Claims 3 and 12-15

Claims 3 and 12-15 stand rejected under 35 U.S.C. § 102(e) as anticipated by the '379 Patent. The rejection was initially raised in the Office Action dated January 25, 2007, and maintained in the Office Action dated September 5, 2007.

Under 35 U.S.C. § 102, a patent claim is invalid if the claim is anticipated by a prior art reference. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Appellants submit that, under this standard, the Examiner has failed to establish a case for anticipation by the '379 Patent of claim 3, and thus claims 12-15 depending therefrom. In particular, even within the broadest reasonable interpretation, the stent with a sleeve, as described in the '379 Patent, fails to anticipate every element of the stent graft as presently claimed.

Claim 3, and thus also dependent claims 12-15 depending therefrom, comprises a stent graft, comprising an endoluminal stent and a graft, and further comprising a vessel wall irritant. Therefore, the claimed subject matter requires at least three elements: a stent, a graft, and a vessel wall irritant. Accordingly, to anticipate the instantly claimed invention, the '379 Patent must teach or disclose a device having at least all three of these elements. Appellants submit that the '379 Patent fails to teach, disclose, or even suggest two of the three required elements, namely, the graft and the vessel wall irritant. Appellants further submit that the Action has failed to provide adequate rationale for citing the '379 Patent as anticipating all three of these required elements. The '379 Patent teaches only a stent having a coating or a sleeve at one or both ends. As taught in the '379 Patent, the coating or sleeve is designed to provide a smooth

surface at one or both ends of the stent to prevent damage to the vessel wall, and thus to prevent formation and proliferation of scar tissue, which may occur upon insertion of an unmodified stent into a vessel. The '379 Patent further teaches that the coating or sleeve may include a bioadhesive to repair the tissue wall in the event of a tear or dissection.

Appellants strongly disagree with the assertion in the Office Action dated September 5, 2007, that the '379 Patent "discloses a stent graft comprising a stent (44) and a graft (46) ...." The Action attempts to further explain this assertion as follows:

> Examiner's position is that with a broadest reasonable interpretation, the sleeve (46) of Wang reference encompasses a graft function and it is considered to be a graft. The sleeve (46) is a tube that has a stent (44) to hold the sleeve open and permit attachment of the sleeve to a body passageway. The sleeve is (46) adapted to prevent the flow of fluids from the inside to the outside of the sleeve. The claimed limitations do not exclude a sleeve (46) placed on the stent (44) from being a graft and the claimed limitations do not limit the claim the stent as claimed to be used for bypassing a damaged body passageway.

Appellants submit that this explanation does not appear to accurately represent the structure or function of a stent graft or the disclosure of the '379 Patent. In particular, Appellants submit that the sleeve positioned at one or both ends of a stent, as disclosed in the '379 Patent, does not encompass the function of a graft in a stent graft. Appellants further submit that the '379 Patent does not describe or even suggest that the sleeve is a tube having a stent to hold it open and to permit its attachment to a body passageway. Appellants thus submit that the sleeve does not correspond to a graft and that the '379 Patent does not disclose a graft attached to the stent.

Nevertheless, in view of these assertions, Appellants wish to further clearly distinguish the stent taught in the '379 Patent as having a sleeve at one or both ends from the stent graft to which the currently pending claims are directed. Accordingly, Appellants submit in particular that a graft is a tubular structure that serves to transport fluid without flow or leakage of fluid through its walls. A stent is a tubular structure with walls made from an open material, such as a wire mesh. Since fluid can freely flow through the open structure of the walls, a stent cannot serve to transport fluid. A stent

graft is a graft, typically of a form in which some or all of the graft is associated with a stent. Certain forms of stent grafts may have short portions of the ends of the stent extending beyond the ends of the graft. However, there appear to be no stent grafts described in the art wherein the graft portions are associated only with one or both ends of the stent. Accordingly, since graft material forms at least most of the entire length of the structure of a stent graft, no flow or leakage of fluid occurs through the walls of the stent portion of the stent graft, except possibly at the very ends of the stent in those cases wherein the ends of the stent extend beyond the ends of the graft. A stent graft, like a graft, can thus serve to transport fluid and is a least functionally primarily still a graft. A variety of commercially available stent grafts clearly demonstrate such devices are structurally and functionally grafts having stents associated therewith, including, for example, the AneuRx AAAdvantage Stent Graft (http://www.medtronic.com/physician/aneurx/index.html (*see,* Evidence Appendix, Item IX.1)); the Talent Thoracic Stent Graft System (http://medgadget.com/archives/2007/03/talent_thoracic.html (*see,* Evidence Appendix, Item IX.2)); and the FLAIR Endovascular Stent Graft (http://www.fda.gov/cdrh/mda/docs/P060002.html (*see,* Evidence Appendix, Item IX.3)). These were previously presented in Appellants' Pre-Appeal Brief Request for Review submitted March 5, 2008.

Appellants submit that, in clear contrast to a stent graft, as described above, the stent taught in the '379 Patent, having sleeves at one or both ends, cannot serve to transport fluid through its length, but only possibly at one or both ends, where it is covered by a sleeve. Fluid will still freely flow through all other portions of the walls that are not covered by a sleeve. Accordingly, Appellants submit that a stent partially covered with a sleeve at one or both ends, even with the broadest reasonable interpretation, is not structurally or functionally equivalent to a stent graft, such as any of those commercially available, as identified above. To further clarify, it may be useful to consider one of the common exemplary uses of a stent graft, such as to span and provide

an alternative passageway for the flow of blood from one side to the other of a portion of a blood vessel having an aneurysm, wherein it is the tubular graft that transports blood through the passageway, with the stent portion exerting radial pressure to simply hold the tubular graft open and forcing the outer surface of the graft against the inner surface of the vessel wall. The stent taught in the '379 Patent, having open mesh walls with a sleeve at one or both ends, would fail in this common use of a stent graft, or for that matter any other use of a stent graft. Even if one were to very broadly interpret the disclosure of the '379 Patent to include devices wherein the sleeves at both ends were long enough to meet in the central portion of the stent, the device would still allow flow, or at least leakage, of blood outward through the walls of the stent at the junction of the two sleeves. Accordingly, Appellants submit that the '379 Patent clearly fails to teach, disclose, or even suggest, a stent graft.

Appellants further disagree with the assertion in the Office Action of September 5, 2007, which is simply a reiteration of the assertion in the Action of January 25, 2007, that the '379 Patent "discloses a stent graft ... wherein the grafts include a vessel wall irritant." Appellants submit that the '379 Patent does not in fact teach, disclose, or even suggest a device having a vessel wall irritant. As the basis for this rejection, the Action cites from the '379 Patent column 7, lines 5-21, and, presumably, although incompletely identified, column 8, lines 20-57. Within the cited passages, the '379 Patent discloses that a coating or sleeve applied to a stent may include a "bioadhesive". The '379 Patent does not teach, disclose, or even suggest, nor does the Action provide any basis in the art or documentary evidence, that bioadhesives, in general, or any of those specifically disclosed in the '379 Patent are vessel wall irritants. The '379 Patent does not teach, discuss, or even suggest, use of a bioadhesive or any other agent as an irritant to induce or accelerate an *in vivo* fibrotic reaction between a stent and tissue of a vessel wall in the vicinity of the stent. In fact, quite to the contrary, as noted above, the '379 Patent describes the use of the sleeve or a coating at the ends of the stent to <u>prevent</u> the formation of scar tissue resulting from damage to the tissue

caused by the ends of the stent. Accordingly, not only does the '379 Patent fail to teach, disclose, or even suggest a vessel wall irritant or a device comprising a vessel wall irritant, the '379

Patent teaches away from Appellants' claimed subject matter.

In summary, Appellants thus respectfully submit that Wang fails to disclose "a stent graft, comprising an endoluminal stent and a graft, wherein said stent graft further comprises a vessel wall irritant...," as claimed in instant claim 3, and thus in claims 12-15, and in claims 4 and 11 as well, all of which depend directly or indirectly from claim 3. Accordingly, Appellants request that the rejection of claims 3 and 12-15 be withdrawn.

Rejection under 35 U.S.C. § 103(a)

Claims 4 and 11

Claims 4 and 11 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the '379 Patent. The rejection was initially raised in the Office Action dated January 25, 2007, and maintained in the Office Action dated September 5, 2007.

Appellants submit that the Examiner has failed to establish a *prima facie* case of obviousness. In particular, the Examiner has incorrectly characterized the '379 Patent, and it does not serve as the basis for an obviousness rejection of pending claims 4 and 11.

The Action asserts in numbered paragraph 5 at page 4 that the '379 Patent "discloses all the limitations of the claims except fails to disclose a stent-graft being bifurcated and the wall irritant being selected from the groups as listed in claim 4." As discussed in detail above concerning the 35 U.S.C. § 102 rejection, the '379 Patent teaches a stent, but fails to teach, disclose, or even suggest, a graft or a vessel wall irritant, *i.e.*, two of the three required elements in claim 3 (and thus in claims 4 and 11, which depend therefrom). There is no further disclosure in the '379 Patent, nor is there any further rationale provided in the Action related to claims 4 and 11, to overcome these deficiencies in the '379 Patent. The Action asserts that "it would have

providing a stent with a bifurcated configuration does not overcome the failure of the '379 Patent to teach a stent graft. In fact, with a bifurcated stent, it is impossible to envision inserting one or more ends of the stent into sleeve(s), as disclosed in the '379 Patent, to form a non-leaking bifurcated alternative fluid passageway. The Action further asserts, regarding claim 4, that "it would have been [an] obvious matter of design choice to use the bioadhesive materials as claimed for Wang's stent graft ...." Recitation of the specific materials in claim 4 provides no basis to overcome the failure of the '379 Patent, as discussed above, to teach, disclose, or suggest, vessel wall irritants. The Action has simply asserted that the vessel wall irritants, which claim 4 requires, encompass the "bioadhesives" of the '379 Patent, without providing any basis in the art, or a declaration of Examiner's personal knowledge, to even suggest that these recited materials are known to be vessel wall irritants. Appellants thus submit that, in the rejection under 35 U.S.C. § 103(a), nothing has been provided in the Action or in the '379 Patent to overcome the failure of the '379 Patent to teach, disclose, or suggest, two of the three required elements in pending claim 3 and thus claims 4 and 11 depending therefrom. Accordingly, the Action has failed to establish a prima facie case for obviousness of claims 4 and 11 under Section 103(a).

In view of the above arguments, Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness. Accordingly, Appellants respectfully request that the obviousness rejection be withdrawn.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

3. A stent graft, comprising an endoluminal stent and a graft, wherein said stent graft further comprises a vessel wall irritant and wherein when implanted into a blood vessel, said stent graft induces or accelerates an *in vivo* fibrotic reaction at a tissue in the vicinity of said stent graft.

4. The stent graft according to claim 3 wherein said vessel wall irritant is selected from the group consisting of talcum powder, metallic beryllium, and silica.

11. The stent graft according to claim 3 wherein said stent graft is bifurcated.

12. The stent graft according to claim 3 wherein said stent graft is a tube graft.

13. The stent graft according to claim 12 wherein said stent graft is cylindrical.

14. The stent graft according to claim 3 wherein said stent graft is self-expandable.

15. The stent graft according to claim 3 wherein said stent graft is balloon-expandable.

IX. EVIDENCE APPENDIX

A copy of each of the following items of evidence is labeled with the respective item number and included herewith:

IX-1. AneuRx AAAdvantage Stent Graft (http://www.medtronic.com/physician/aneurx/index.html).

IX-2. Talent Thoracic Stent Graft System (http://medgadget.com/archives/2007/03/talent_thoracic.html).

IX-3. FLAIR Endovascular Stent Graft (http://www.fda.gov/cdrh/mda/docs/P060002.html).

X. RELATED PROCEEDINGS APPENDIX

None

IX-1

Medtronic

AneuRx AAAdvantage Stent Graft System

Product Features & Specifications

Surgical

Clinical

Reference

Patient

Indic

Contra

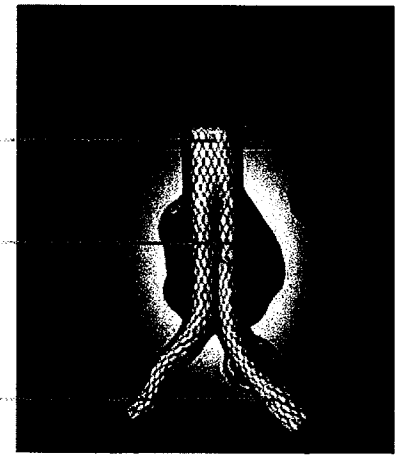
Warnin

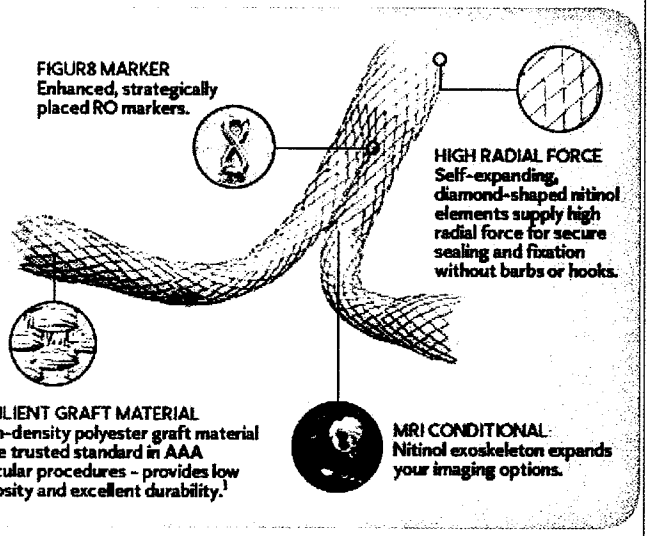
Precau

Adver

AneuRx AAAdvantage Stent Graft System

The **AAAdvantage stent graft** is designed to offer longer fixation zones, enhanced control and more options.





EXPERIENCE CONTROL OPTIONS

References
1. Data on file at Medtronic, Inc.

Additional Information

- Contact Medtronic Vascular
- aneurxaaadvantage.com

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IX-2

medGadget
internet journal of emerging medical technologies

Monday, March 5, 2007

Talent™ Thoracic Stent Graft System

Cardiac Surgery Vascular Surgery

Medtronic, Inc. has just submitted the final pre-market approval documents to the FDA for its Talent™ Thoracic Stent Graft System. At the present time there is no evidence to expect that the FDA would create any hurdles for the company to commercially market and sell its endovascular system for descending thoracic aneurysms.

From the press release:

> Minimally invasive therapies, such as endovascular stent grafting, provide potential benefits including reduced surgical morbidity, reduced hospital stay, and an improved quality of life. The procedure involves threading the stent graft through a small opening in the femoral artery of the leg. The stent graft is advanced under fluoroscopic guidance to the site of the thoracic aortic aneurysm, where it is then positioned and deployed from the delivery system. Once deployed, the stent graft expands to fit snugly within the diameter of the aorta, providing a new path for the blood flow.
>
> Medtronic has been at the forefront of the endovascular stent graft industry, with more clinical research and product implants than any other company. Its long history includes more than 100,000 patients treated with aortic stent grafts dating back to 1996. In addition to the Talent Thoracic stent graft, the company also markets the Valiant Thoracic Stent Graft System outside the United States. Medtronic also offers two stent grafts for abdominal aortic aneurysms (AAA): the Talent Abdominal Stent Graft system outside the U.S. and the popular AneuRx® AAAdvantage Abdominal Stent Graft system in the U.S.

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IX-3

New Device Approval

FLAIR Endovascular Stent Graft - P060002

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness Data (SSED) and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: FLAIR Endovascular Stent Graft
PMA Applicant: Bard Peripheral Vascular
Address: 1625 West 3rd Street, Tempe, AZ 85280-1740
Approval Date: July 23, 2007
Approval Letter: http://www.fda.gov/cdrh/pdf6/p060002a.pdf

What is it? The FLAIR Endovascular Stent Graft is used to treat a stenosis, a narrowing or blockage, which has developed at the connection of a vein and an arteriovenous (A-V) access graft, known as the venous anastomosis. An A-V access graft acts as an artificial blood vessel that can be used repeatedly to draw blood with a needle during hemodialysis. The FLAIR Endovascular Stent Graft is a flexible, self-expanding tube made of ePTFE (expanded polytetrafluoroethylene) and a metallic support structure known as a stent, which holds the device open within the vein and A-V access graft. The stent graft is compressed into the end of a long, thin, tube-like device called a delivery catheter so that it can be implanted in the body.

The FLAIR Endovascular Stent Graft is the first endovascular system approved to treat a stenosis at the venous anastomoses of an A-V access graft.

How does it work? The FLAIR Endovascular Stent Graft is used after balloon inflation is performed to open the narrowed segment in the A-V access graft. The delivery catheter containing the endovascular graft is inserted into the A-V access graft and placed across the narrowed segment that has just been opened with the balloon. The endovascular graft is then released and self-expands so that it is pressing against the A-V access graft and blood vessel to keep the area open.

When is it used? The FLAIR Endovascular Stent Graft can be used to support or hold open a narrowed